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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/955,373 10/21/97 MOURITSEN

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HM12/0714

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EXAMINER

SCHWADRON, R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1644

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DATE MAILED: 07/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

| | |
|----------------------------------|---|
| Application No. 08/955,373 | Applicant(s) Mouritsen et al. |
| Examiner Ron Schwadron, Ph.D. | Group Art Unit 1644 |



- Responsive to communication(s) filed on _____.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 26, 28-43, 45, and 46 is/are pending in the application.
- Of the above, claim(s) 29-43 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 26, 28, 45, and 46 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claims _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____.
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election with traverse of Group VI, claims 26,28-43,45,46 in Paper No. 16 is acknowledged. The traversal is on the ground(s) that are elucidated in Paper No. 16. This is not found persuasive because of the following reasons. Regarding applicants comments on page 5 of Paper No. 16, the Patent Office interprets independent and distinct as reading on distinct (see M.P.E.P. 802.01, July 1998, page 800-2). Regarding Groups II and III, Group II is drawn to a composition comprising a modified self-protein or the modified self protein, classified in Class 424, subclass 184.1 and Class 530, subclass 350, while Group III is drawn to a composition comprising cytokine conjugates, classified in Class 424, subclass 192.1 These products are structurally and functionally distinct and have different uses. The cytokine conjugate composition contains a cytokine not found in the modified self protein composition. Therefore they are novel and unobvious in view of each other and are patentably distinct. Regarding applicants comments about undue burden, the M.P.E.P. § 803 (July 1998) states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the examination of additional Groups II and III. Regarding Group I and Groups II/III, Inventions I and II/III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed product can be made by chemical synthesis using art known methods of peptide synthesis.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13-25,27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 16.

3. Applicant's election of species of Group A in Paper No. 19 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the

restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 29-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected species. Election was made without traverse in Paper No. 19.

5. Claims 26,28,45 and 46 are under consideration. Claims 13-25,27,44 have been cancelled.

6. Drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 enclosed with paper no. 6.

7. Applicant needs to amend the specification to recite the SEQ. ID. no. where a sequence is disclosed in the specification. See 37 CFR 1.821 (d).

8. Claims 26,28,45,46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite in the recitation of "essentially preserve the overall tertiary structure" because it is unclear what this means or encompasses. It is unclear what changes to the tertiary structure would or would not be encompassed by the aforementioned term. For example, it is unclear if this term encompasses changes at the physical/chemical level (eg. crystal structured) or simply functional changes (eg. still immunogenic antigen as evidenced by antibody binding by antibodies specific for unmodified antigen). If the term is interpreted as encompassing changes at the physical/chemical level, it is unclear as to what deviations from the normal crystal structure would or would not be encompassed by the term "essentially preserve the overall tertiary structure". Claim 46 is indefinite in the recitation of "flanking regions because it is unclear what this term means or encompasses.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 26,28,45,46 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell-Jones et al. (WO 92/05192).

Russell-Jones et al. teach T cell epitopes derived from Trat protein (see Abstract). Russell-Jones et al. teach Trat T cell epitopes are inserted into proteins, wherein the insertion of said peptide increases the antibody response against the protein into which Trat has been inserted (see page 4, lines 24-26 and Abstract). Russell-Jones et al. teach that the Trat peptide is inserted such that the protein still functions as an immunogen. The Trat peptide has been inserted into the immunogen in such a manner as to "essentially preserve the overall tertiary structure", because the ability of the immunogen to function as an immunogen is maintained (see page 8, first complete paragraph). Russell-Jones et al. teach that the Trat modified immunogen can be used as a vaccine in a composition containing an adjuvant such as saponin (see page 8 and 13). Russell-Jones et al. teach that using recombinant DNA technology that Trat peptide can be inserted into the immunogen via substituting Trat peptide for a peptide contained in said molecule (see page 32 and page 31, first incomplete paragraph). Said insertion would preserve flanking regions on both sides of the Trat T cell epitope. The Trat peptide has been inserted into the immunogen in such a manner as to "essentially preserve the overall tertiary structure", because the ability of the immunogen to function as an immunogen is maintained. Russell-Jones et al. teach that immunogens used in the aforementioned vaccines can include self proteins such as luteinizing hormone, somatostatin, inhibin, FSH (see page 9 and claim 12). Russell-Jones et al. teach that such vaccines can be used in animals and humans.

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group

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Art Unit 1644

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1600 at (703) 305-3014.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600



Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
July 13, 1999